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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,543	01/07/2002	Roberto Reniero	112843-031	7133
29174	7590	10/20/2004	EXAMINER	
BELL, BOYD & LLOYD, LLC P. O. BOX 1135 CHICAGO, IL 60690-1165			WARE, DEBORAH K	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/936,543

Applicant(s)

RENIERO ET AL.

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10/6/04
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 12, 14, 15 are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 12, 14, 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Claims 1, 6-12, and 16-22 are presented for examination on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Continued Prosecution Application***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 6, 2004, and August 20, 2004, have been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-12 and 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is rendered vague and indefinite for the recitation of "an ingestable support material" because it is uncertain whether a food composition is intended. It is suggested to change "an ingestable support material" to --a food composition-- . Also the "step of using" is unclear with respect to what is actually being done to carry out the

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step. Thus, it is suggested to change “using” to –adding to a food material--. Like wise it is suggested to change claim 7 at line 2, from “ingestable support material” to –food composition--. Further, in claim 8 it is suggested to delete “ingestable support material is a” and to change “food composition” at line 2 to –food material--.

Claim 9 is rendered vague and indefinite for the recitation of “a disorder associated with” wherein it is unclear what this means in the claim. It is suggested to delete this phrase to define the claim because the metes and bounds of the claim can not be determined.

Also claim 10 is rendered vague and indefinite in that it does not clearly read on a pharmaceutical and it is suggested that at the last line after the strain identifier to insert --, and wherein said composition contains a pharmaceutically acceptable carrier--. Cancellation of claim 11 is suggested because there appears to be no difference between the pharmaceutical and the food composition per se. Claims 11 and claim 21 appear to be essential duplicates. Likewise claims 10 and 20 appear to be essential duplicates. Also cancellation of claims 20-22 is requested.

Claim 12 is rendered vague and grammatically indefinite for the recitation of “to grow in” and it is suggested to change the phrase to –of growing in--.

Claim 16 is rendered vague and indefinite for “an ingestable support material” for those reasons discussed above and the same change is requested, deletion of “comprises an ingestable support material” and insertion of –is in a food composition when administered—in order to adequately define the method from which it depends.

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Also claim 17 to be consistent with changes suggested above is suggested to be changed from "support material" at line 2 to --food composition--. Also the term "the lactic acid bacaterium strain" lacks antecedent basis and claim dependency should be changed from claim 9 to claim 16.

Claim 18 is rendered vague and indefinite for failing to define the step of administering and this also does not distinguish from a step of treating per se. It is suggested to insert --to a human or animal susceptible to having diarrhea--after "administering" at line 2. Further, the claim is indefintie and vague for "a disorder associated with" as discussed above.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1 and 20-22 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 3 as well as claims 22-23 of copending Application No. 09/936,489. This is a provisional double patenting rejection since the

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conflicting claims have not in fact been patented, however, the identical claims have been allowed.

Claims 1 and 10 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 6 and 18 of copending Application No. 09/936, 542.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6-12 and 16-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 7-20 and 22-23 of copending Application No. 09/936,489. Although the conflicting claims are not identical, they are not patentably distinct from each other because of those reasons of record in the last office action of April 6, 2004.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Applicants have conceded in their response of August 24 2004, that they will file a terminal disclaimer.

Claims 1, 6-12 and 16-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 and 4-22 of copending Application No. 09/936,542. Although the conflicting claims are not identical, they are not patentably distinct from each other because of those reasons of record in the last office action of April 6, 2004.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants have conceded in their response of August 24 2004, that they will file a terminal disclaimer.

All claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**DEBORAH K. WARE**  
**PATENT EXAMINER**  
Deborah K. Ware  
October 16, 2004